

**In the Claims**

Please amend the claims as follows:

1. (Original) A method to determine the risk of progression of a prostate cancer patient after therapy, comprising:
  - a) detecting or determining the amount or level of complex formation between a blood plasma sample obtained from a patient after therapy for prostate cancer and an agent that binds to TGF- $\beta_1$ , IGFBP-2, or IGFBP-3, so as to form a complex; and
  - b) correlating the amount or level of complex formation with the risk of progression.
2. (Original) A method to determine the prognosis of a prostate cancer patient after therapy, comprising:
  - a) detecting or determining the amount or level of complex formation between a blood plasma sample obtained from a patient prior to or after therapy for clinically localized prostate cancer and an agent that binds to TGF- $\beta_1$ , IGFBP-2, IGFBP-3, IL-6 or IL-6sR so as to form a complex; and
  - b) correlating the amount or level of complex formation with the risk of non-prostate confined disease.
3. (Original) The method of claim 1 or 2 wherein the sample is obtained at one to two months after therapy.
4. (Original) The method of claim 1 wherein the clinical stage of the patient is T3a, T3, T2c, T2b, T2a, T2, T1c, T1b, T1a or T1.
5. (Original) The method of claim 2 wherein the amount or level of complex formation is correlated to an increased risk of biochemical progression or to final pathological stage.
6. (Original) The method of claim 1 or 2 wherein the therapy is primary therapy.

7. (Original) The method of claim 1 or 2 wherein the agent is an antibody.
8. (Original) The method of claim 7 wherein the antibody is a polyclonal antibody.
9. (Original) The method of claim 7 wherein the antibody is a monoclonal antibody.
10. (Original) The method of claim 1 or 2 wherein the therapy is surgery, radical prostatectomy, radiation therapy or a radioactive seed implant.
11. (Original) The method of claim 1 or 2 wherein the cancer exhibits extracapsular extension or seminal vesicle involvement or wherein the patient does not have detectable metastases.
12. (Original) The method of claim 1 or 2 further comprising:
  - c) contacting a second blood sample obtained from the patient at a later point in time with the agent so as to form a complex; and
  - d) comparing complex formation in a) to complex formation in c) and determining whether the level or amount of complex formation in c) is different than the level or amount of complex formation in a).
13. (Original) The method of claim 1 or 2 further comprising detecting or determining the amount or level of a molecule other than TGF- $\beta_1$ , IGFBP-2 or IGFBP-3 which is a marker for prostate cancer.
14. (Original) The method of claim 2 further comprising detecting or determining the amount or level of a molecule other than IL-6 or IL-6sR which is a marker for prostate cancer.
15. (Original) The method of claim 13 or 14 wherein the other marker is selected from the group consisting of PSA, UPA, UPAR, PAI-1, IGFBP-3, p53, p21, and E-cadherin.

16. (Original) The method of claim 13 or 14 wherein the other marker is a serum protein.
17. (Original) The method of claim 1 or 2 further comprising determining PSA levels or Gleason scores.
18. (Original) The method of claim 1 or 2 wherein the patient has not been subject to hormonal therapy.
19. (Original) The method of claim 1 or 2 wherein complex formation is detected or determined with an agent that specifically binds the complex.
20. (Original) The method of claim 1 wherein complex formation is detected or determined with a second agent that binds TGF- $\beta_1$ , IGFBP-2, or IGFBP-3.
21. (Original) The method of claim 2 wherein complex formation is detected or determined with a second agent that binds TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR or IGFBP-3.
22. (Original) The method of claim 20 or 21 wherein the agent is an antibody.
23. (Original) The method of claim 1 or 2 wherein the agent is detectably labeled or binds to a detectable label.
24. (Original) The method of claim 19 wherein the agent that binds the complex is detectably labeled or binds to a detectable label.
25. (Original) The method of claim 7 wherein the antibody is detectably labeled or binds to a detectable label.
26. (Original) The method of claim 1 or 2 wherein the correlating of the amount or level of complex formation to the risk is conducted by a computer.

27. (Original) The method of claim 1 or 2 wherein the blood plasma sample is a platelet poor plasma sample.
28. (Original) An apparatus, comprising:  
a data input means, for input of test information comprising the level or amount of at least one protein in a sample obtained from a mammal, wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2, and IGFBP-3;  
a processor, executing a software for analysis of the level or amount of the at least one protein in the sample;  
wherein the software analyzes the level or amount of the at least one protein in the sample and provides the risk of disease progression in the mammal.
29. (Original) An apparatus, comprising:  
a data input means, for input of test information comprising the level or amount of at least one protein in a sample obtained from a mammal, wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR and IGFBP-3;  
a processor, executing a software for analysis of the level or amount of the at least one protein in the sample;  
wherein the software analyzes the level or amount of the at least one protein in the sample and provides the risk of non-prostate confined disease in the mammal.
30. (Original) The apparatus of claim 28 or 29 wherein the amount or level is input manually using the data input means.
31. (Original) The apparatus of claim 28 or 29 wherein the software constructs a database of the test information.
32. (Original) The apparatus of claim 28 or 29 wherein the information further comprises the amount or level of PSA, UPA, UPAR, PAI-1, p53, p21, and E-cadherin.

33. (Original) The apparatus of claim 28 or 29 wherein the information further comprises a Gleason score.

34. (Currently Amended) A method to determine the prognosis of a prostate cancer patient after therapy, comprising:

- a) ~~inputting~~ providing test information to a data input means, wherein the information comprises the level or amount of at least one protein in a sample obtained from a prostate cancer patient, and wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2 and IGFBP-3;
- b) executing a software for analysis of the test information; and
- c) analyzing the test information so as to provide the risk of disease progression in the patient.

35. (Currently Amended) A method to determine the prognosis of a prostate cancer patient after therapy, comprising:

- a) ~~inputting~~ providing test information to a data input means, wherein the information comprises the level or amount of at least one protein in a sample obtained from a prostate cancer patient, and wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR and IGFBP-3;
- b) executing a software for analysis of the test information; and
- c) analyzing the test information so as to provide the risk of non-prostate confined disease in the patient.

36. (New) A nomogram for determining the risk of progression of prostate cancer after therapy or the risk of non-prostate confined disease in a prostate cancer patient comprising: at least one correlation, wherein the at least one correlation includes the correlation of the level or amount of at least one protein in a sample obtained from a prostate cancer patient and the risk of progression or the risk of non-prostate confined disease in the patient, and wherein the protein is selected from the group consisting of

**PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT**

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TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR and IGFBP-3.